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L5: Entry 25 of 28 File: JPAB Oct 20, 1988

PUB-NO: JP363253022A
DOCUMENT-IDENTIFIER: JP 63253022 A
TITLE: BACLOFEN PHARMACEUTICAL FOR EXTERNAL USE

PUBN-DATE: October 20, 1988

INVENTOR-INFORMATION:
NAME COUNTRY
WATANABE, SHIGEYUKI
SATO, SUSUMU

ASSIGNEE-INFORMATION:
NAME COUNTRY
NITTO ELECTRIC IND CO LTD

APPL-NO: JP62086354
APPL-DATE: April 8, 1987

INT-CL (IPC): A61K 31/195; A61K 31/195; A61K 47/00; A61K 47/00

ABSTRACT:

PURPOSE: To obtain a pharmaceutical for external use, containing baclofen, as necessary, with a percutaneous absorption adjuvant or cyclodextrin and capable of exhibiting sustained drug effects without side effects on digestive systems, hallucination, dependence, etc.

CONSTITUTION: A pharmaceutical obtained by containing β-(aminomethyl)-p-chlorohydrocinnamic acid (baclofen) expressed by the formula, as necessary, with a percutaneous absorption adjuvant, e.g. 6~12C alcohol and organic solvent (e.g. lower alcohol or propylene glycol) or cyclodextrin in a base, such as ointment base, solvent or tacky agent. Water-solubility of the baclofen is improved by blending the cyclodextrin and percutaneous absorbability is improved without depositing crystals.

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☐ 1: Drug Alcohol Depend. 1993 Sep;33(2):157-63.

Baclofen administration for the treatment of affective disorders in alcoholic patients.

Krupitsky EM, Burakov AM, Ivanov VB, Krandashova GF, Lapin IP, Grinenko AJa, Borodkin YuS.

Leningrad Regional Dispensary of Narcology, Russia.

Ninety alcoholic patients with the secondary affective disorders (anxiety, depression) were divided into four groups. Patients in the first group received GABAB receptor ligands (baclofen), those in the second group, diazepam, those in the third group, amitriptyline and those in the fourth group, placebo. The results of clinical, psychological (tests of Spielberger, Zung and MMPI), and electrophysiological (superslow omega-potential) investigations showed that baclofen is an effective drug for affective disturbances in alcoholic patients, with efficacy superior to placebo and equal to diazepam and amitriptyline. At the same time baclofen does not have the side-effects and complications of the latter. Significant changes in platelet MAOB activity and the dopamine, serotonin and GABA concentrations in blood after treatment were not found in the four patient groups. The peripheral matabolism of GABA and monoamines do not seem to be related to the development of secondary affective disorders in alcoholic patients. This investigation encourages the search for drugs acting on the affective psychopathology of GABAB receptor ligands.

Publication Types:
- Clinical Trial
- Randomized Controlled Trial

PMID: 8261880 [PubMed - indexed for MEDLINE]

☐ 1: Alcohol Clin Exp Res. 2000 Jan;24(1):58-66.

Ability of baclofen in reducing alcohol intake and withdrawal severity: I--Preclinical evidence.

Colombo G, Agabio R, Carai MA, Lobina C, Pani M, Reali R, Addolorato G, Gessa GL.

CNR Center for Neuropharmacology, Bernard B. Brodie Department of Neuroscience, University of Cagliari, Italy. colomb@unica.it

BACKGROUND: The similarities between the pharmacological effects of the gamma-aminobutyric acid receptor agonist, baclofen, and the alcohol-substituting agent, gamma-hydroxybutyric acid, led us to investigate whether baclofen was capable of reducing (a) ethanol withdrawal syndrome in ethanol-dependent rats and (b) voluntary ethanol intake in ethanol-preferring rats. METHODS: In experiment 1, Wistar rats were rendered physically dependent on ethanol by the repeated administration of intoxicating doses of ethanol for 6 consecutive days. Baclofen was acutely administered intraperitoneally at doses of 10, 20, and 40 mg/kg. In experiment 2, baclofen (0, 2.5, 5, and 10 mg/kg, intraperitoneally) was administered once a day for 14 consecutive days to ethanol-preferring sP rats that had continuous access to ethanol (10%, v/v) and water under the two-bottle free choice regimen. RESULTS: In experiment 1, baclofen dose-dependently decreased the intensity of ethanol withdrawal signs; furthermore, 20 mg/kg of baclofen protected from audiogenic seizures in ethanol-withdrawn rats. In experiment 2, baclofen selectively and dose-dependently reduced voluntary ethanol intake; a compensatory increase in water intake left total fluid intake virtually unchanged. CONCLUSIONS: These results are in close agreement with those of a preliminary clinical study and suggest that baclofen may constitute a novel therapeutic agent for alcoholism.

PMID: 10656194 [PubMed - indexed for MEDLINE]

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☐ 1: Broadbent J, Harless WE. Related Articles, Links

Differential effects of GABA(A) and GABA(B) agonists on sensitization to the locomotor stimulant effects of ethanol in DBA/2 J mice.
Psychopharmacology (Berl). 1999 Jan;141(2):197-205.
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Putative oxidative metabolites of 1-methyl-6-hydroxy-1,2,3,4-tetrahydro-beta-carboline of potential relevance to the addictive and neurodegenerative consequences of ethanol abuse.
Alcohol. 1997 May-Jun;14(3):213-23.
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The sequential use of clonidine and naltrexone in the treatment of opiate addicts.
Adv Alcohol Subst Abuse. 1984 Spring;3(3):19-39. Review.
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☐ 1: Alcohol. 1999 Apr;17(3):231-40.

The effects of the GABA(B) agonist baclofen on the temporal and structural characteristics of ethanol intake.

Smith BR, Boyle AE, Amit Z.

Center for Studies in Behavioral Neurobiology, Concordia University, Montreal, Quebec, Canada. smith@csbn.concordia.ca

The present study examined the behavioral processes mediating the influence of the GABA(B) agonist baclofen on the maintenance of voluntary ethanol intake. Long-Evans rats were randomly assigned to two groups, one receiving baclofen (10 mg/kg, IP) and the other an equal volume of saline. Subjects were presented with a free choice of ethanol (10% v/v) and water immediately following drug injections, which occurred every other day. The results demonstrated that baclofen treatment resulted in an overall increase in the intake of absolute ethanol but failed to influence the intake of water. In contrast, food intake was substantially attenuated as evidenced by a decrease in the number of pellets consumed in subjects treated with baclofen. A microanalysis of the patterns of food and fluid bouts indicated that the enhanced ethanol intake was primarily a function of an increase in the frequency of ethanol bouts. In contrast, the decrease in food intake appeared to be a reflection of a decrease in the size of the food meals but not their frequency. An analysis of the temporal pattern of intake over the 23-h test sessions indicated that baclofen treatment produced a biphasic effect on ethanol intake with a slight decrease in intake during the first hour following treatment. Baclofen-treated animals then were observed to consume greater amounts of ethanol than did saline controls throughout the remainder of the dark cycle as well as into the light cycle. Although ethanol intake gradually decreased in controls throughout the light cycle, baclofen-treated subjects maintained a consistent level of intake throughout this period. Furthermore, there was a clear dissociation between the temporal pattern of ethanol intake and that of food and water, as intake of the latter substances was shown to decrease during the first hour following injection, but unlike with ethanol, no increase in intake was observed during the remainder of the test session. The nature of the effects of baclofen observed in the present study would suggest that the GABA(B) receptor system may not play a central role in the mediation of voluntary ethanol intake.

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Effect of baclofen on alcohol and sucrose self-administration in rats.
Alcohol Clin Exp Res. 2003 Jun;27(6):900-8.
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2: Colombo G, Serra S, Brunetti G, Vacca G, Carai MA, Gessa GL. Related Articles, Links

Suppression by baclofen of alcohol deprivation effect in Sardinian alcohol-preferring (sP) rats.
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Ventral tegmental area region governs GABA(B) receptor modulation of ethanol-stimulated activity in mice.
Neuroscience. 2002;115(1):185-200.
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Different control of GH secretion by gamma-amino- and gamma-hydroxy-butyric acid in 4-year abstinent alcoholics.
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Ability of baclofen in reducing alcohol intake and withdrawal severity: I--Preclinical evidence.
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Alcohol. 1998 Nov;16(4):325-8.
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Putative oxidative metabolites of 1-methyl-6-hydroxy-1,2,3,4-tetrahydro-beta-carboline of potential relevance to the addictive and neurodegenerative consequences of ethanol abuse.
Alcohol. 1997 May-Jun;14(3):213-23.
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☐ **10:** Krupitskii EM, Burakov AM, Grinenko AIa, Borodkin IuS. Related Articles, Links

[Effect of pharmacotherapy of affective disorders on the psycho-semantics of alcoholic patients]
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☐ **14:** Cott J, Carlsson A, Engel J, Lindqvist M. Related Articles, Links

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